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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/074,644 05/08/98 ANDERSON

C 1373-DARPA

FRANCIS A COOCH
THE JOHNS HOPKINS UNIVERSITY
APPLIED PHYSICS LAB / PATENT COUNSEL
11100 JOHNS HOPKINS ROAD
LAUREL MD 20723-6099

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EXAMINER

PHAM, M

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

12/01/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/074,644

Applicant(s)

ANDERSON ET AL.

Examiner

Minh-Quan K. Pham

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 29-31 and 41-46 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24 is/are allowed.
- 6) ☒ Claim(s) 1-23, 25, 32-37, 40 and 47-50 is/are rejected.
- 7) ☒ Claim(s) 26-28 and 38-39 is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 May 1998 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892) 17) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 18) ☐ Notice of Informal Patent Application (PTO-152)
- 16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 19) ☐ Other: ____.

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of claims 1-28, 32-40, and 47-50 in Paper No. 5 is acknowledged.

Claims 29-31, 41-45, and 46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: 10 in Figure 1 and 12 in Figure 2. Correction is required.

Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-4,14-23, 33, and 40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 3-4,14-23, 33, and 40 recite a mean for providing a non-naturally fluorescing analyte with fluorescence by the addition of fluorescent tags to the analyte. This ensures that fluorescence is detected; however, it does not allow for the quantification of the amount of analyte as there is no way of knowing whether the fluorescence comes from the unbounded fluorescent tags or from the bounded fluorescent tags (the fluorescent tag bounded to the analyte). In order to quantify the analyte, it is necessary to separate the unbounded fluorescent tags from the bounded fluorescent tags. Since a mean for separating unbounded fluorescent tag is missing from the specification, one skilled in the relevant art would have to surmise that the inventors, at the time the application was filed, do not have possession of the claimed invention.

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Claims 3-4,14-23, 33, and 40 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A mean for separation to separate the bounded fluorescent tag from the unbounded fluorescent tag critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Claims 3-4,14-23, 33, and 40 are drawn to a mean of providing a non-naturally fluorescing analyte with fluorescence by the addition of fluorescent tags to the analyte. This ensures that fluorescence is detected; however, it does not allow for the quantification of the amount of analyte as there is no way of knowing whether the fluorescence comes from the unbound fluorescent tags or from the bounded fluorescent tags (the fluorescent tag bounded to the analyte). In order to quantify the analyte, it is necessary to separate the unbounded fluorescent tags from the bounded fluorescent tags. Since the mean for separating unbounded fluorescent tag is missing from the disclosure, the claims are rejected as being based on a disclosure which is not enabling.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1, 5, 32, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenney et al. (US Pat. 4,802,981 and 4,861,488) in view of Carman et al.

Kenney et al. disclose an automatic immunoaffinity chromatography apparatus comprising

- a column packed with material bounded with immunological material to extract analyte from the sample;
- means for automatic control;
- means for supplying an eluent;
- means for loading a sample;
- means for monitoring and controlling flow rate;
- means for detecting the analyte

(see column 1, lines 48-68; column 2, lines 1-22 and lines 47-57; and column 3, lines 16-46).

Kenney et al., however, differ from the claimed invention because they do not disclose the use of fluorescence to detect and quantify the amount of analyte in the sample.

Carman et al. disclose a robotic, automated immunoaffinity column-based method for analysis of aflatoxin in food using fluorescence detection (see Abstract).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use fluorescence detection, as taught by Carman et al., in the apparatus of Kenney et al. because fluorescence detection is relatively simple to use and highly sensitive.

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Claims 1, 5-6, 32, 34-35, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al. in view of Carman et al.

Thomas et al. disclose an apparatus for immunoaffinity chromatography comprising

- a column packed with antibody-bounded silica;
- means for automatic control;
- means for supplying an eluent;
- means for supplying a wash fluid;
- means for loading a sample;
- means for monitoring and controlling flow;
- means for detecting the analyte

(see Figure 2; and page 3824, Instrumentation).

Thomas et al. differ from the claim invention because they do not disclose the use to fluorescence to detect and quantify the amount of analyte in the sample.

Kenney et al., however, differ from the claimed invention because they do not disclose the use to fluorescence to detect and quantify the amount of analyte in the sample.

See above for the disclosure of Carman et al.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use fluorescence detection, as taught by Carman et al., in the apparatus of Thomas et al. because fluorescence detection is relatively simple to use and highly sensitive.

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Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kenney et al. (US Pat. 4,802,981 and 4,861,488) in view of Carman et al. as applied to claims 1, 5, 32, and 34 above, and further in view of Annino et al. (US Pat. 5,340,543).

See above for the disclosure of Kenney et al. in view of Carman et al.

Kenney et al. in view of Carman et al., however, differ from the claimed invention because they do not disclose the use of self-contained, modular unit in the sensor.

Annino et al. disclose a chromatography device for analyzing samples wherein the device is configured so that it is a modular unit (see Abstract).

Therefore, it would have been obvious to one of ordinary skill the art at the time the invention was made to use modular units, as taught by Annino et al., in the sensor of Kenney et al., as modified by Carman et al. because modularity enables repairs to be quickly effected on the sensor and greatly simplifies the task of accessing the components of the sensor.

Claims 7, 47, and 49-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al. in view of Carman et al. as applied to claims 1, 5-6, 32, and 34 above, and further in view of Annino et al. (US Pat. 5,340,543).

See above for the disclosure of Thomas et al. in view of Carman et al.

Thomas et al. in view of Carman et al., however, differ from the claimed invention because they do not disclose the use of self-contained, modular unit in the sensor.

See above for the disclosure of Annino et al. (see Abstract).

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Therefore, it would have been obvious to one of ordinary skill the art at the time the invention was made to use modular units, as taught by Annino et al., in the sensor of Thomas et al., as modified by Carman et al., because modularity enables repairs to be quickly effected on the sensor and greatly simplifies the task of accessing the components of the sensor.

Claims 14-19, 25-26, 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al. in view of Carman et al. as applied to claims 1, 5-6, 32, and 34 above, and further in view of Feldman et al. (US Pat. 5,399,866).

See above for the disclosure of Thomas et al. in view of Carman et al.

Thomas et al. in view of Carman et al., however, differ from the claim invention because they do not disclose the optical system of the fluorescence detector.

Feldman et al. disclose an optical system for the detection of signal in fluorescent immunoassay. This system comprises two optical apparatuses, one for focusing the radiation on to the analyte and one for focusing the emitted fluorescent light on to the detector; various filters and mirrors for directing the radiation; an amplifier to measure the output of the detector. The radiation source can be an arc lamp or a laser (see Figure 1; column 1, lines 61-68; column 2, lines 1-13 and lines 55-64; and column 3, lines 16-29).

Therefore, it would have been obvious to one of ordinary skill the art at the time the invention was made to include the fluorescence detector of Feldman et al. in the apparatus of Thomas et al., as modified by Carman et al., because the fluorescence detector, as taught by

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Feldman et al, has the advantage of flexibility, not requiring precise alignment and positioning of each of the elements (see column 1, lines 47-54).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al. in view of Carman et al., and further in view of Feldman et al. (US Pat. 5,399,866) as applied to claims 14-19, 25-26, 36-37 above, and further in view of Kenny et al. (US Pat. 5,491,344).

See above for the disclosure of Thomas et al. in view of Carman et al., and further in view of Feldman et al.

Thomas et al. in view of Carman et al., and further in view of Feldman et al.; however, differ from the claimed invention because they do not disclose the use of a photomultiplier tube as a detector.

Kenny et al. disclose a system for analyzing chromatography column effluent using fluorescence spectroscopy wherein the detector is a photomultiplier tube (see Abstract; and column 7, lines 30-41).

Therefore, it would have been obvious to one of ordinary skill the art at the time the invention was made to use a photomultiplier tube to detect fluorescence in the apparatus of Thomas et al., as modified by Carman et al. and Feldman et al., because the photomultiplier tube can achieve a high dynamic range, as per the teaching to Kenny et al. (see column 7, lines 34-39).

Allowable Subject Matter

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Claims 26-28, and 38-39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Since these claims are free of prior art, they would be allowable if rewritten so that they are not dependent on a rejected base claim.

Claim 24 is allowed because it is free of prior art.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ruhn et al., Kumazawa et al. (US Pat. 4,937,200), Sportsman (US Pat. 5,491,096), and Velander et al. (US. Pat. 5,328,603) are cited to show apparatuses and methods for immunoaffinity chromatography.

Tindle et al. (US Pat. 3,744,219) is cited to show a chromatography system.

Buettner (US Pat. 5,834,318) and Umrigar et al. (US Pat. 5,487,998) are cited to show apparatus and methods in affinity purification.

Cheung et al. (US Pat. 5,074,977) is cited to show a digital biosensor for the detection of ligand binding.

Potter (US Pat. 5,205,291) is cited to show the use of electronic circuits in a fluorescence sensor to filter signals.

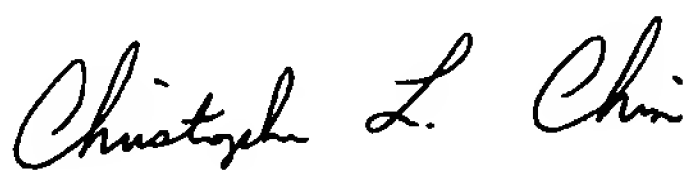
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Quan K. Pham whose telephone number is (703) 305-1444. The examiner can normally be reached on Monday to Friday, 8 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Minh-Quan K. Pham, Ph.D.
November 29, 1999


CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/641